UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/201,228	11/30/98	GRIFFAIS R	9710-004

HM12/1009

PENNIE & EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036-2711

EXAMINER	
MARSCHEL, A	
ART UNIT	**PAPER NUMBER**
1631	6

DATE MAILED: 10/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/201,228	Griffais et al.
Examiner	**Art Unit**
Ardin Marschel	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 23, 2001*

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-3 and 8-58* is/are pending in the applica

4a) Of the above, claim(s) *17-29, 31-50, and 53-56* is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-3, 8-16, 30, 51, 52, 57, and 58* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-3 and 8-58* are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Applicants' arguments, filed 7/23/01, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 57 and 58 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are

considered, a sufficient amount for a *prima facie* case are discussed below.

This is a new ground of rejection necessitated by the addition of claims 57 and 58 which now cite deposits of clones. The enablement of such clones is lacking until deposit requirements have been met such as under the Budapest Treaty with assurances of permanent public access and term of deposit as outlined in the MPEP deposit requirements.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and

any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1-3, 8-16, 30, 51, 52, 57, and 58 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

This rejection is reiterated and maintained from the previous office action, mailed 4/17/01, and as necessitated by amendment regarding newly added claims. Applicants argue that the merely isolation of sequences from an organism makes them unique. This is not understood because the concept of evolutionary conserved genes which link large numbers of organisms is well known. Thus, uniqueness of a nucleic acid sequence is available as a known and usable characteristic only

after verifying that the sequence is not conserved over other closely or even distantly related organisms. It is noted that applicants have not substantiated this uniqueness characterization regarding whether the claimed sequences are or are not conserved or, in fact, only present in the cited *Chlamydia trachomatis*. Thus, the utility of these sequences requires further research regarding this issue. It is noted that applicants further set forth PCR usage as well as hybridization probe usage but again without any information as to whether these sequences are unique or conserved versus other organisms.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 8-16, 30, 51, 52, 57, and 58 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility, or, alternatively, a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention. This rejection is reiterated and as necessitated by amendment for the same reasons as noted above for the lack of utility rejection.

Claims 1-3, 8-16, 30, 51, 52, 57, and 58 are rejected under

35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This lack of written description rejection is reiterated from the previous office action, mailed 4/17/01, and as necessitated by amendment regarding newly added claims. Applicants argued this rejection based on novel and non-obvious open reading frame considerations as well as the known ability to insert such sequences into vectors etc. This is confusing and non-persuasive because this rejection is based on a lack of written description of sequences beyond the cited SEQ ID NO: sequences.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 51, 52, 57, and 58 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by the remaining Genbank sequence listed below for the instantly elected SEQ ID NO. wherein it has greater than 80% identity and thus also hybridize

under high stringency conditions to the instant sequences or their full and exact complement of the same length. The 102(a) versus 102(b) type of Genbank sequence is determined by the publication date for each sequence where 102(a) sequences were published as prior art on or after November 28, 1996 and 102(b) prior art sequences were published before November 28, 1996.

Instant SEQ ID NO:	Genbank acc. no.	% similarity	102 sec.
1089	M74221	99.115	102(b)

This rejection is reiterated and maintained from the previous office action, mailed 4/17/01, and as necessitated by amendment regarding newly added claims which are deemed to include subsequences therein.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35

U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-3, 9-11, 13, 15, 51, 52, 57, and 58 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the below GenBank sequences corresponding to each instant elected SEQ ID NO.

The sequences disclosed in the Genbank sequence alignments as listed below are disclosed as to one strand but are prepared as cDNAs from isolated mRNAs which suggests and motivates complements thereof as well as host cells which must contain operatively linked regulatory sequences in order for these sequences to have been grown and isolated therefrom. It is noted that the instant claims are not limited as to what % complementarity is meant by the stringency or hybridizability limitations in the claims.

Instant SEQ ID NO:	Genbank acc. no.
1089	M74221

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to prepare the mRNAs, cDNAs, host cells containing them, in vectors with operative regulatory sequences thus resulting in embodiments of the instant invention. This rejection is reiterated and maintained from the previous office action, mailed 4/17/01, and as necessitated by amendment regarding newly added claims.

Claim 30 is rejected under 35 U.S.C. § 103(a) as being unpatentable over the above listed GenBank sequence corresponding

to each instant elected SEQ ID NO:, taken in view of Southern et al.(P/N 5,436,327).

The above sequence match describe a nucleic acid within the scope of the instant claims as being of interest. Southern et al. describes the preparation and use of DNA chips whereon such nucleic acids of interest are immobilized.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to immobilize interesting nucleic acids as listed above as motivated and suggested regarding such immobilization by Southern et al. thus resulting in the practice of instant claim 30. This rejection is reiterated and maintained from the previous office action, mailed 4/17/01. It is noted that the above SEQ ID NO: 1089 is matched by the above noted Genbank sequence and supports this rejection contrary to arguments of applicants which have not specifically argued what is different from the above sequence match compared to the instant claim 30 limitations.

No claim is allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED

STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

This application contains claims 17-29, 31-50, and 53-56 drawn to an invention non-elected with (effectively without) traverse in Paper No. 8, filed 8/16/00. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (37 C.F.R. § 1.144) M.P.E.P. § 821.01.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

October 5, 2001

Ardin H. Marschel

ARDIN H. MARSCHEL
PRIMARY EXAMINER